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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,874	12/15/2005	Toshiya Kai	IWT-001	6777

20374 7590 06/03/2009

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EXAMINER	
KISHORE, GOLLAMUDI S	
ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
06/03/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/534,874	KAI ET AL.	
	Examiner	Art Unit	
	Gollamudi S. Kishore, Ph.D	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-13 and 17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 4-13 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment dated 2-25-09 is acknowledged.

Claims included in the prosecution are 1, 4-13 and 17. In view of the amendments, the 112 rejections and the 102 rejection over Kamps is withdrawn.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1, 4-13 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kamps (BBA, 19960) by itself or in combination with Tardi (J. Immunological Methods, 1997) and Yu (US 2003/0166864).

Kamps as discussed in the prior action discloses liposomes, which have both albumin and PEG, are bonded (abstract, Materials and Methods). Although Kamps does not specifically teach the encapsulation of an active agent, on page 184, col. 1 teaches that liposomes have been proven to be a suitable delivery system for various kinds of therapeutics including cytostatics and virostatics. Therefore, it would have been obvious to one of ordinary skill in the art to encapsulate any therapeutic agent in Kamps liposomes, depending upon the disease to be treated with a reasonable expectation of

success. One skilled in the art would be motivated to encapsulate therapeutic agents such as doxorubicin (anti-cancer agent) since the reference of Tardi shows the knowledge in the art of the routine encapsulation of these agents in similar liposomes. Kamps also is lacking in the teaching of recombinant HSA (human serum albumin). However, in the absence of showing the criticality, it is deemed obvious to one of ordinary skill in the art to use either purified HSA or that produced by recombinant techniques with a reasonable expectation of success since both have the same sequence of amino acids. One skilled in the art would be motivated to use either recombinant HSA or natural one because of the equivalency taught by Yu (0140, 0162, 0266, 0296, 0427, and 0455).

3. Claims 1, 4-13 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tardi (J. Immunological methods, 1997) by itself or in combination with Jacobson (US 2002/0132328) or Mayo (US 2002/0146406).

Tardi discloses liposomes which have both ovalbumin and PEG on their surfaces and such liposomes are immunogenic. The liposomes further contain doxorubicin. Ovalbumin is modified with the amine reactive cross linker SPDP according to the procedures of Loughery (using N- (3-(2-pyridyldithio) propionyl) phosphatidylethanolamine), which is cited of interest (abstract, Materials and Methods, Figure 1). Tardi however, does not teach the binding of recombinant human serum albumin. The use of serum albumin instead of ovalbumin would have been obvious to one of ordinary skill in the art since a similar binding occurs. One of ordinary skill in the art would be motivated to use serum albumin instead of ovalbumin because of the

equivalency between ovalbumin and human serum albumin taught by Jacobson (0123) or Mayo (0059). It would have been obvious to one skilled in the art to use a recombinant HAS instead of naturally occurring HSA with a reasonable expectation of success since both have the same sequence of amino acids.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant points out to Fig. 1 in Tardi and argues that it shows faster plasma elimination of PEG-liposomes when ovalbumin is associated. This argument is not persuasive. Instant claims now recite the presence of a biologically active agent and Tardi clearly states that the elimination of ovalbumin liposomes is because of the anti-ovalbumin antibodies and when no anti-ovalbumin antibodies were detected when the liposomes used contained doxorubicin (abstract). Furthermore, it would have been obvious to one of ordinary skill in the art that when ovalbumin is administered to humans, it would induce the production of anti-ovalbumin antibodies, being antigenic to human.

4. Claims 1, 4-13 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tardi (J. Immunological methods, 1997) by itself or in combination with Jacobson (US 2002/0132328) or Mayo (US 2002/0146406) as set forth above, further in view of Yu (US 2003/0166864).

The teachings of Tardi, Jacobson and Mayo have been discussed above. What is lacking in these references is the teaching of the use of recombinant HSA. One skilled in the art would be motivated to use either recombinant HSA or natural one because of the equivalency taught by Yu (0140, 0162, 0266, 0296, 0427, and 0455).

5. Claims 1, 4-13 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zalipski (6,180,134) in view of Kamps (BBA, 1996) optionally in combination with Jacobson or Mayo cited above or vice versa (Kamps and optionally either Jacobson or Mayo in view of Zalipski.

Zalipsky while disclosing liposomal formulations wherein the liposomal surface is attached to both PEG and protein teaches that the protein coupled to PE-PEG maleimide was much higher than either the MPB maleimides (Fig. 9; col. 11, line 62 through col. 13, line 10).

Kamps discloses liposomes, which have both albumin and PEG, are bonded (abstract, Materials and Methods).

Jacobson and Mayo each teach the equivalency between ovalbumin and human serum albumin.

The attachment of serum albumin taught by Kamps as the protein in Zalipsky would have been obvious to one of ordinary skill in the art with a reasonable expectation of success since albumin is a protein and one would expect similar attachment. Alternately to attach albumin to PEG-PE of the liposomes of Kamps would have been obvious to one of ordinary skill in the art since more albumin can be attached as taught by Zalipsky and because more protein can be attached as taught by Zalipsky. The use of human serum albumin instead of ovalbumin would have been obvious to one of ordinary skill in the art because of the equivalency taught by Jacobson and Mayo.

This rejection is maintained because applicant has not provided any specific arguments regarding Zalipski.

6. Claims 1, 4-13 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zalipski (6,180,134) in view of Kamps (BBA, 1996) optionally in combination with Jacobson or Mayo cited above or vice versa (Kamps and optionally either Jacobson or Mayo in view of Zalipski) as set forth above, further in view of Yu (US 2003/0166864).

The teachings of Zalipski, Kamps, Jacobson and Mayo have been discussed above. What is lacking in these references is the teaching of the use of recombinant HSA. One skilled in the art would be motivated to use either recombinant HSA or natural one because of the equivalency taught by Yu (0140, 0162, 0266, 0296, 0427, and 0455).

1. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Krass Frederick can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gollamudi S Kishore/
Primary Examiner, Art Unit 1612

GSK